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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,599	04/13/2001	Yuji Ishihara	2566USOP	9278

23115 7590 09/24/2003

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
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LINCOLNSHIRE, IL 60069

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT PAPER NUMBER

1624

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/807,599**

Applicant(s)  
**ISHIHARA et al.**

Examiner  
**Brenda Coleman**

Art Unit  
**1624**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 24, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-12, 14, 15, 17, 22, 43, and 44 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7, 9-11, 14, 15, 17, 22, 43, and 44 is/are allowed.
- 6) ☒ Claim(s) 8 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

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### DETAILED ACTION

Claims 1-5, 7-12, 14, 15, 17, 22, 43 and 44 are pending in the application.

This action is in response to applicants' amendment filed June 24, 2003. Claim 13 has been canceled and claims 12, 14 and 17 have been amended.

#### *Response to Amendment*

Applicant's amendments filed June 24, 2003 have been fully considered with the following effect:

1. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 13 and 17 of the last office action, which is hereby **withdrawn**.
2. With regards to the 35 USC § 112, first paragraph rejection of claim 12 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants indicated that "claim 12 is an independent claim" and that "the twelfth compound of claim 12 is supported both *specifically* in the specification as Example 90 appearing on page 216 of the specification; and also *generally* by the description of R<sup>1</sup> in the specification". However, while it is acknowledged that claim 12 is independent, the twelfth species is not within the scope of the genus nor is it positively described in the specification. The applicants further provide a breakdown of the compound of example 90 in Appendix A where the applicants describe the support for the N,N-diethylaminomethyl)phenyl)methyl moiety of R<sup>1</sup>. First, the support for the twelfth species of claim 12 is not the salt of example 90. Second, the applicants allege support for

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benzyl on page 23, lines 29-30 which is accepted; methyl on page 23, line 9 which is part of the definition of  $R^1$  not a substituent on  $R^1$ ; and diethylamino on page 25, lines 8-10 which is accepted. But support for the methyl group of the N,N-diethylaminomethylphenylmethyl cannot be found within the definition of  $R^1$ , but must be a substituent on  $R^1$  for the twelfth species to be within the genus of formula I.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For reasons of record and stated above.

3. The applicant's amendments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection of claim 12 of the last office action, which is hereby **withdrawn**.

4. With regards to the 35 U.S.C. § 101 rejection of claim 12 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants stated that "the twelfth compound of claim 12 is supported both *specifically* in the specification as Example 90 appearing on page 216 of the specification; and also *generally* by the description of  $R^1$  in the specification". However, the statement of intended use is directed to the compounds of formula I of which this species does not belong.

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Claim 12 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. For reasons of record and stated above.

In view of the amendment dated June 24, 2003, the following new grounds of rejection apply:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 8 is vague and indefinite in that it does not end with a period indicating the end of the claim.

***Allowable Subject Matter***

6. Claims 1-5, 7, 9-11, 14, 15, 17, 22, 43 and 44 allowed. None of the prior art of record nor a search in the pertinent art area teaches the compounds, compositions, method of use or process of preparing the compounds of formula (I) as claimed herein.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*Brenda Coleman*

Brenda Coleman  
Primary Examiner AU 1624  
September 22, 2003